Exhibit F

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

IN THE MATTER OF CIVIL ACTIONS AGAINST MERCK & CO., INC., AS LISTED IN ATTACHMENT 1

ORDER TO STAY

Defendant Merck & Co., Inc. ("Merck") removed these 11 negligence and products liability actions from New York State Supreme Court pursuant to 28 U.S.C. §§ 1332, 1441, and 1446. A list of these 11 actions (identified in order of the WDNY civil docket number) is attached to this Order.

Plaintiffs, who are represented by same law firm, allege claims against Merck concerning the manufacture, sale, and distribution of the prescription drug Vioxx. Plaintiffs also named as defendants a number of New York corporations that operate pharmacies throughout the State. In its notices of removal, however, Merck argued that the pharmacy defendants were fraudulently joined because no reasonable basis exists for plaintiffs' negligence and products liability claims against them.

Merck has filed motions to stay the actions pending the issuance of conditional orders by the Judicial Panel on Multidistrict Litigation ("JPML") transferring the cases as "tag-along" actions to *In re Vioxx Marketing, Sales Practices and Products Liability Litigation*, MDL No. 1657, an MDL action that has been established in the Eastern District of Louisiana.[1]

For the reasons set forth in this Court's Decision and Order in two other nearly identical

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[1] On February 16, 2005, the Panel transferred 138 civil actions to the MDL, which involve common questions of fact concerning the alleged increased health risks associated with the anti-inflammatory drug, Vioxx. Since that time, more than 3,000 additional actions have been transferred to the MDL, and it appears that the number continues to grow.

actions, *North v. Merck*, 2005 WL 2921638 (W.D.N.Y. Nov. 4, 2005) and *Krieger v. Merck*, 2005 WL 2921640 (W.D.N.Y. Nov. 4, 2005), I find that Merck's motions to stay should be granted in these 11 cases as well. The objectives of the MDL process, that is the avoidance of inconsistent rulings and the conservation of judicial resources, are best met by allowing the MDL court here to resolve any issues regarding whether these actions were properly removed.

CONCLUSION

Merck's motions to stay (Dkts.#4) are **GRANTED**.

IT IS SO ORDERED.

DAVID G. LARIMER
United States District Judge

Dated: Rochester, New York
March 1, 2006.

ATTACHMENT 1

Campbell v. Merck & Co., Inc., et al	05-CV-6740L
Paterniti v. Merck & Co., Inc., et al	06-CV-6065L
Adams v. Merck & Co., Inc., et al	06-CV-6066L
Grace v. Merck & Co., Inc., et al	06-CV-6067L
Stroka v. Merck & Co., Inc., et al	06-CV-6068L
Stenzel v. Merck & Co., Inc., et al	06-CV-6069L
Porter v. Merck & Co., Inc., et al	06-CV-6070L
Ciura v. Merck & Co., Inc., et al	06-CV-6074L
Lukasik v. Merck & Co., Inc., et al	06-CV-6075L
Yates v. Merck & Co., Inc., et al	06-CV-6096L
Dempsey v. Merck & Co., Inc., et al	06-CV-6097L

Exhibit G

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

In Re: VIOXX Products Liability Litigation This Document Relates to: STATE OF LOUISIANA, ex rel. CHARLES C. FOTI, JR., ATTORNEY GENERAL Representative Plaintiff versus MERCK & CO., INC., Defendant Case No. 05-3700	MDL NO. 1657 SECTION: L HON. ELDON E. FALLON MAG. JUDGE KNOWLES

FIRST SUPPLEMENTAL AND AMENDING COMPLAINT FOR INJUNCTIVE RELIEF AND DAMAGES

NOW COME PETITIONERS, CHARLES C. FOTI, JR., a person of the full age of majority, and who currently holds the position of Attorney General for the State of Louisiana, as *parens patriae* on behalf of the State of Louisiana and its citizens, THE STATE OF LOUISIANA (the "State"), and the LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALS ("DHH") (hereinafter sometimes referred to collectively as "Petitioners"), and bring this action for injunctive relief, restitution and other damages under the laws of the State of

Louisiana against the above-named defendant. This case involves the non-steroidal anti-inflammatory drug rofecoxib designed, formulated, promoted, sold and distributed by the defendant in the United States as Vioxx® ("Vioxx") from May, 1999 until its withdrawal from the market on September 30, 2004. Vioxx, as compared to other drugs in its class, caused a high incidence of injury among those individuals who ingested Vioxx, including, but not limited to heart attacks, strokes, sudden cardiac death, or death. For their Petition against the Defendant, Petitioners assert the following:

1.

Made Defendant herein is the following party:

A. **MERCK & CO., INC.**, a foreign corporation licensed to do and doing business in Louisiana, is a New Jersey corporation with its principal place of business in New Jersey. At all times relevant hereto, Merck & Co., Inc. was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third-parties or related entities, the pharmaceutical prescription drug Vioxx® ("Vioxx" or the "Product"). Petitioners allege on information and belief that Merck & Co., Inc. does business in Louisiana and the Parish of Orleans and that at all times relevant hereto it developed, manufactured, and sold in interstate commerce and in Louisiana, Parish of Orleans, the aforementioned product.

3.

Petitioners bring this action pursuant to Louisiana Constitution Art. 4, §8, La. Rev. Stat. Ann. §§ 13:5036, and 51:1401, et seq., including, but not limited to §§ 51:1405, 1407, 1408, and 1409, to obtain permanent injunctive relief, restitution, other monetary damages, costs of this suit, reasonable attorney's fees, and any and all other, further, and different relief to which Petitioners may be entitled against the Defendant by reason of the Defendant's violations of law.

4.

The acts charged in this Petition as having been done by the Defendant, were authorized, ordered and/or done by its officers, agents, employees, or representatives while actively engaged in the management and conduct of the Defendant's business or affairs.

5.

This Court has personal jurisdiction over the Defendant because the Defendant is doing business or has done business in the State of Louisiana and in this judicial district to meet due process requirements as the Defendant, directly or through agents acting with actual and/or apparent authority, has:

(a) transacted business in this state;

(b) contracted to supply or obtain services or goods in this state;

(c) intentionally availed itself of the benefits of doing business in this state;

(d) produced, promoted, sold, marketed and/or distributed its products or services in this state and, thereby, has purposefully profited from its access to this state's markets;

(e) caused tortious damage by act or omission in this state;

(f) caused tortious damage in this state by act or omission committed outside this state while (i) regularly doing or soliciting business in this state and/or (ii) engaging in other persistent courses of conduct within this state and/or (iii) deriving substantial revenue from goods used or consumed or services rendered in this state; and

(g) committed acts and omissions which the Defendant knew or should have known would cause damage and, in fact, did cause damage in this state to the Petitioners while (i) regularly doing or soliciting business in this state, and/or (ii) engaging in other persistent courses of conduct within this state and/or (iii) deriving substantial revenue from goods used or consumed or services rendered in this state.

FACTUAL ALLEGATIONS

6.

This case involves a prescription drug whose chemical name is rofecoxib, that was designed to treat osteoarthritis, rheumatoid arthritis, acute pain, and migraines. Rofecoxib was designed, formulated, patented, marketed, sold, and ultimately distributed by the Defendant under the brand name "Vioxx".

7.

Osteoarthritis, or degenerative joint disease, is characterized by the breakdown of the joint's cartilage (which cushions the ends of bones). Cartilage breakdown causes bones to rub against each other, leading to pain and loss of movement. Rheumatoid arthritis is a chronic syndrome characterized by inflammation in the lining of the joints, causing pain, stiffness, warmth, redness and swelling, leading to pain and loss of movement.

8.

Vioxx is in a class of drugs called non-steroidal anti-inflammatory drugs ("NSAIDs"). Vioxx reduces substances that cause inflammation, pain and fever. Prostaglandins are chemicals that are important in promoting inflammation and its symptoms (pain, fever, swelling and tenderness). Vioxx blocks an enzyme named COX-2 that makes prostaglandins thereby reducing the amounts of prostaglandins, and reducing inflammation and its symptoms.

9.

The United States Food and Drug Administration ("FDA") first approved Vioxx in May, 1999 for the reduction of pain and inflammation caused by osteoarthritis, acute pain and menstrual pain. Vioxx was subsequently approved to treat rheumatoid arthritis in adults and children.

10.

In June 2000, Merck submitted a safety study to the FDA entitled "Vioxx Gastrointestinal Outcomes Research" or "VIGOR" that found an increased risk of serious cardiovascular events, including heart attacks and strokes in patients taking Vioxx.

11.

In February, 2001, the FDA consulted its Arthritis Advisory Committee regarding the clinical interpretation of this new safety information.

12.

In April, 2001, the FDA implemented labeling changes which included information about the increase in risk of cardiovascular events, including heart attacks and strokes.

13.

Other studies recently suggested an increased risk of cardiovascular events, and the FDA was in the process of reviewing these studies to determine if further labeling changes were needed.

14.

On September 30, 2004, Merck voluntarily withdrew Vioxx from the market after the data safety monitoring board overseeing a long-term study of the drug recommended that the study be halted because of an increased risk of serious cardiac events, including heart attack and strokes. The risk was approximately twice that of individuals taking a placebo.

15.

Annual sales of Vioxx total approximately $2.5 billion.

16.

The Defendant aggressively marketed and sold Vioxx by misleading potential users about the product and by failing to adequately warn users of serious dangers which the Defendant knew or should have known resulted from the use of Vioxx. The Defendant widely and successfully marketed Vioxx in Louisiana and throughout the United States in order to induce widespread use. This marketing campaign resulted in numerous individuals taking Vioxx, including many Louisiana residents, and suffering serious injuries as a result, all at a time when other safer, less expensive, efficacious drugs were available. Furthermore, on information and belief, by requesting that Vioxx be placed on Louisiana's Medicaid formulary, the Defendant directly or implicitly represented to Petitioners that Vioxx was safe.

17.

On information and belief, from the time that the Defendant started developing Vioxx through the date on which the Defendant withdrew Vioxx from the market, the Defendant engaged in knowing misrepresentations with respect to the safety of Vioxx. These misrepresentations include, but are not limited to, Defendant's advertising and promotional campaigns touting Vioxx's safety; the Defendant's suppression of evidence, including its own medical/clinical research, showing that Vioxx was unsafe and posed a significant increased risk of heart attack, stroke, and other cardiovascular and/or cererbrovascular problems; and Defendant's practice of threatening and/or intimidating those physicians and scientists who attempted to protect the public by exposing Vioxx's serious, and sometimes deadly, side effects, complications, and consequences.

18.

Had the Defendant disclosed the risks and dangers associated with Vioxx, Louisiana citizens would not have taken Vioxx or been subject to its catastrophic side effects. Moreover, Petitioners would not have paid substantial sums for Louisiana Medicaid recipients' Vioxx prescriptions or still more substantial sums for the medical expenses incurred due to Louisiana Medicaid recipients' Vioxx-related injuries.

19.

On information and belief, as a result of the manufacturing, marketing, selling and distributing of Vioxx, the Defendant has reaped billions of dollars in profits at the expense of the health of individuals, including the citizens of Louisiana.

PETITIONERS WERE DAMAGED BY THE DEFENDANT'S WRONGFUL CONDUCT

20.

The Defendant falsely and deceptively misrepresented or omitted a number of material facts concerning Vioxx, including, but not limited to, adverse health effects caused by Vioxx including the frequency, severity and rapid development of these adverse events.

21.

Furthermore, through, among other things, its advertising campaigns, misleading communications with and concealment of information from the FDA, the medical community and the public, and despite its knowledge that Vioxx was dangerous, the Defendant continued to vigorously promote and advertise Vioxx.

22.

While Vioxx was on the U.S. Market, Petitioners paid a substantial amount of money for the cost of filling Vioxx prescriptions for citizens of Louisiana.

23.

The Defendant knew or should have known that Vioxx created significant risks of serious injuries, including damage to the heart, cardiovascular system, and other organs. The Defendant failed to make proper, reasonable, timely or adequate warnings about the risks associated with the use of Vioxx.

24.

By way of its wrongful misconduct, the Defendant intended to supply and did supply Vioxx to Louisiana consumers, including Louisiana Medicaid recipients, that was unreasonably dangerous and in certain instances, deadly.

25.

As a result of the Defendant's fraudulent concealment, the applicable statutes of limitations have been tolled as to all of the claims of Petitioners.

26.

Petitioners state, and intend to state, causes of action solely under the laws of the State of Louisiana and specifically are not attempting to state a cause of action under the laws of the United States of America.

27.

As a result of the manufacture, distribution, delivery and sale of the Defendant's products to purchasers within the State of Louisiana, directly or through its subsidiaries, affiliates or agents, the Defendant obtained the benefits of the laws of the State of Louisiana for its products.

FIRST CAUSE OF ACTION: REDHIBITION

28.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth here, and further allege as follows:

29.

At all times pertinent herein, the Defendant marketed, sold, and distributed Vioxx for use by consumers, including citizens of Louisiana.

30.

The Defendant is liable to Petitioners under the Louisiana law of Redhibition because, at the time it manufactured Vioxx and sold Vioxx to citizens of Louisiana, Vioxx contained

redhibitory defects, and the Defendant knew or, alternatively, should have known, of such redhibitory defects and failed to disclose and/or concealed such defects.

31.

Had the citizens of Louisiana known of such redhibitory defects, they would not have purchased Vioxx, nor would Petitioners have approved and paid for such purchases.

32.

Had the Petitioners known of such redhibitory defects, Petitioners would not have paid for Vioxx use by Louisiana citizens.

33.

Under the Louisiana laws of Redhibition, the Defendant is liable to Petitioners for a return of the purchase price, including interest, all expenses occasioned by the sale, all damages sustained by Petitioners, as well as costs, penalties, and reasonable attorneys' fees.

SECOND CAUSE OF ACTION: STRICT LIABILITY AND FAILURE TO WARN

34.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth here, and further allege as follows:

35.

The drug Vioxx is an unreasonably dangerous product as defined by Louisiana Revised Statute 9:2800.1 *et seq.* (the Louisiana Products Liability Act) and the defendant manufacturer is liable for all injuries proximately caused thereby.

36.

The drug Vioxx was defective at the time of its manufacture, development, production,

testing, inspection, endorsement, prescription, sale and distribution, in that, and not by way of limitation, said product and its warnings, instructions and directions failed to warn of the dangerous propensities of Vioxx, which risks were known or reasonably scientifically knowable to the Defendant. The Defendant knew or should have known of the defective condition, characteristics and risks associated with Vioxx, as previously set forth herein.

37.

At all times herein mentioned, the aforementioned product was defective, and the Defendant knew that the product was to be ingested by the user without inspection for defects therein. Moreover, the Petitioners and citizens of Louisiana neither knew, nor had reason to know at the time of the use of the subject product, of the existence of the aforementioned defects.

38.

As a result of the defective condition of the aforementioned product, Petitioners are entitled to all the damages as alleged herein.

THIRD CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY

39.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth here, and further allege as follows:

40.

The drug Vioxx is an unreasonably dangerous product as defined by Louisiana Revised Statute 9:2800.51 et seq. (the Louisiana Products Liability Act), and the defendant manufacturer is liable for all injuries proximately caused thereby.

41.

At all times herein mentioned, the Defendant expressly warranted to Petitioners and the Louisiana citizens, and their agents and physicians, by and through statements made by the Defendant or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned product was safe, effective, fit and proper for its intended use.

42.

In purchasing, paying for, and/or utilizing the aforementioned product, Petitioners, the Louisiana citizens, and their agents and physicians relied upon the skill, judgment, representations and foregoing express warranties of the Defendant. Said warranties and representations were false in that the aforementioned product was not safe and was unfit for the use for which it was intended.

43.

As a result of the foregoing breach of express warranties by the Defendant, Petitioners suffered damages as alleged herein.

FOURTH CAUSE OF ACTION: BREACH OF IMPLIED WARRANTY

44.

Petitioners re-allege and incorporate all preceding paragraphs of this petition as if fully set forth here, and further allege as follows:

45.

The drug Vioxx is an unreasonably dangerous product as defined by Louisiana Revised Statute 9:2800.51 et seq. (the Louisiana Products Liability Act) and the defendant manufacturer

is liable for all injuries proximately caused thereby.

46.

At all times pertinent herein, the Defendant marketed, sold, and distributed Vioxx for use by consumers, such as the citizens of Louisiana, and the Defendant knew of the use for which Vioxx was intended and impliedly warranted Vioxx to be of merchantable quality and safe and fit for its intended use.

47.

Petitioners were and are unskilled in the research, design and manufacture of the aforementioned product and reasonably relied entirely on the skill, judgment and implied warranty of the Defendant in using, purchasing, and/or paying for the aforementioned product.

48.

Contrary to such implied warranty, Vioxx was not of merchantable quality or safe and fit for its intended use, because Vioxx was unreasonably dangerous and unfit for the ordinary purposes for which it was used as described herein.

49.

As the proximate result of the Defendant's breach of implied warranty, Petitioners have sustained damages as described herein.

FIFTH CAUSE OF ACTION: UNFAIR TRADE PRACTICES

50.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth herein, and further allege as follows:

51.

The acts committed by the Defendant as alleged herein violate the provisions of the Louisiana Unfair Trade Practices Act ("LUTPA"), La. Rev. Stat. Ann. § 51:1401, et seq. Each of the previously described acts by the Defendant were "unlawful" in that they were "unfair methods of competition and[/or] unfair or deceptive acts or practices in the conduct of [Defendant's] trade or commerce," as prohibited by La. Rev. Stat. Ann. § 51:1405.

52.

As set forth previously, the Defendant has used unfair methods of competition and/or unfair and deceptive acts or practices in the design, manufacturing, and/or marketing of Vioxx and in the course of its business, all of which are unlawful under LUTPA. As Merck voluntarily withdrew Vioxx from the U.S. market, Merck could at any time voluntarily return Vioxx to the U.S. market, which would lead to additional LUTPA violations and would subject the State of Louisiana and its citizens to additional financial losses and damages. Upon information and belief, Merck has already made efforts to return Vioxx to the U.S. market. Petitioner, the Louisiana Attorney General, is specifically authorized under LUTPA to seek to enjoin (temporarily and/or permanently) all such unlawful acts pursuant to La. Rev. Stat. Ann. § 51:1407.

53.

As a direct and proximate result of the Defendant's wrongful conduct in violation of LUTPA, Petitioners have sustained financial losses in amounts as will be established at the trial of this matter, which amounts Petitioners are entitled to recover from the Defendant. Pursuant to LUTPA, Petitioners are entitled to a permanent injunction against the Defendant to prevent them

from returning Vioxx to the Louisiana market (La. Rev. Stat. Ann. § 51:1407) as well as financial restitution and such other ancillary monetary damages sustained by them (La. Rev. Stat. Ann. § 51:1408), all of which will be established at the trial of this matter. Furthermore, Petitioners, the State of Louisiana and/or DHH, which, due to the Defendant's unlawful conduct in violation of LUTPA, spent millions of dollars to purchase Vioxx for persons covered under the Louisiana Medicaid program, are entitled to all remedies afforded under La. Rev. Stat. Ann. §51:1409, including actual damages, reasonable attorney's fees, and costs. Finally, Petitioners seek any and all other and further remedies to which they are entitled under LUTPA.

SIXTH CAUSE OF ACTION: OTHER STATE LAW THEORIES OF RECOVERY

54.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth here, and further allege as follows:

55.

At all times herein mentioned, the Defendant owed a duty to Petitioners to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, prepare for use, sell, prescribe and adequately warn of the risks and dangers of the aforementioned product.

56.

At all times herein mentioned, the Defendant negligently and carelessly manufactured, designed, formulated, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold the aforementioned product and failed to adequately test and warn of the risk and dangers of the aforementioned product.

57.

The Defendant impliedly and/or expressly represented to Petitioners that the drug Vioxx, which they manufactured, distributed and/or sold was safe for use and would not cause the adverse health effects described herein. Despite the Defendant's knowledge to the contrary, the Defendant misrepresented to Petitioners that Vioxx was safe and/or concealed its unsafe propensities from Petitioners. Petitioners relied upon these misrepresentations to their detriment in placing Vioxx on the Louisiana Medicaid formulary and/or paying for Louisiana Medicaid recipients' Vioxx prescriptions.

58.

As a result of said negligence, carelessness, and misrepresentations of the Defendant, Petitioners have suffered damages as alleged herein.

SEVENTH CAUSE OF ACTION: UNJUST ENRICHMENT

59.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth here, and further allege as follows:

60.

The Defendant has been enriched from the selling and manufacturing of a defective product, and Petitioners have been correspondingly impoverished by purchasing or paying for the defective product. There is no justification or cause for Defendants' enrichment or Petitioners' resulting impoverishment.

61.

Defendants' enrichment at the expense or impoverishment of Petitioners is inequitable.

Although Petitioners have alleged that they enjoy remedies at law against Defendant, to the extent that Petitioners do not enjoy a remedy at law, Defendant should be made to return all sums unjustly obtained from Petitioners.

62.

Petitioners demand that Merck & Co., Inc. return all such monies acquired from Petitioners through the selling of Vioxx.

PRAYER FOR RELIEF

WHEREFORE, Petitioners pray as follows:

1. That the unlawful conduct alleged herein be adjudged and decreed to be unlawful and unfair methods of competition and/or unfair and deceptive acts or practices committed by the Defendant as prohibited by La. Rev. Stat. Ann. §51:1405;
2. That, pursuant to LUTPA, Petitioners be granted a permanent injunction against the Defendant to prevent it from returning the drug product trade named "Vioxx" to the Louisiana market;
3. That, pursuant to LUTPA, the Defendant be found liable, in solido, to Petitioners for financial restitution and such other ancillary monetary damages sustained by Petitioners, all of which will be established at the trial of this matter;
4. That, pursuant to LUTPA, the Defendant be found liable, in solido, to Petitioners, the State of Louisiana and/or DHH, for all remedies available to the State of Louisiana and/or DHH under La. Rev. Stat. Ann. §51:1409, including actual damages, reasonable attorney's fees, and costs;
5. That, pursuant to LUTPA, the Defendant be permanently enjoined from any other

conduct complained of herein which is determined to be in violation of LUTPA and/or that the Defendant be found liable, in solido, to Petitioners for any and all other, further, and different remedies to which Petitioners are entitled under LUTPA;

6. That Petitioners be granted all damages to which they are reasonably entitled, including, but not limited to, the return of the purchase price paid by the State of Louisiana's Medicaid program for Vioxx prescriptions,, attorney's fees to the full extent recoverable, all costs, and legal interest from the date of judicial demand until paid, due to Vioxx's redhibitory defects, the Defendant's failure to warn, the Defendant's breach of express and/or implied warranties, the Defendant's deceptive and unfair trade practices, the Defendant's negligence, the Defendant's misrepresentations, and/or the Defendant's unjust enrichment.

7. Petitioners further pray for any and all such other, further and, different relief as the nature of the case may require or as may be deemed just and proper by this Court, including, but not limited to, the recovery of all costs of this suit, judicial interest, and attorney's fees to the fullest extent recoverable by law.

8. Petitioners pray that all deposition and travel expenses be taxed as costs.

Respectfully submitted, this 5th day of May, 2006,

DUGAN & BROWNE, a P.L.C.

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IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT OF
HINDS COUNTY, MISSISSIPPI

JIM HOOD, ATTORNEY GENERAL *ex rel.*,
STATE OF MISSISSIPPI

PLAINTIFF

v.

CIVIL ACTION NO.: G2005-1712 w/f

MERCK & CO., INC.

DEFENDANT

COMPLAINT

The State of Mississippi, through Attorney General Jim Hood, brings this action for monetary damages, civil penalties, declaratory and injunctive relief, restitution, disgorgement of profits and punitive damages on behalf of the State of Mississippi, and on behalf of Mississippi citizens who have paid for the prescription drug Vioxx®, manufactured and marketed by the Defendant, Merck & Co., Inc., as more fully described below:

INTRODUCTION

1. Defendant, Merck & Co., Inc., ("Merck"), has defrauded the State of Mississippi, its agencies and instrumentalities, by knowingly issuing false and misleading statements in order to induce the State, its agencies and instrumentalities to purchase its drug VIOXX®.

2. VIOXX® is a Cox-2 specific inhibitor used in the treatment of inflammation and pain and is among the class of drugs known as NSAIDs. Traditional NSAIDs inhibit both Cox-1 and Cox-2 enzymes. Cox–1 enzyme is believed to have a protective effect on the gastrointestinal system and the traditional NSAIDs were known to pose a risk of ulcer and other gastrointestinal problems. It is alleged herein that Defendant, misrepresented that VIOXX® had a significantly reduced risk of these side effects.

3. VIOXX® was promoted and marketed by Defendant, Merck & Co., Inc., ("Merck") as much safer and more effective drug than the much cheaper NSAIDs already on the

market. In reliance on these claims by Defendant, agencies and instrumentalities of the State approved the inclusion of VIOXX® as a preferred prescription drug and agreed to pay for use of VIOXX® by beneficiaries and members. Defendant initially misrepresented the safety of the drug in order to obtain a position on the State's prescription drug formularies, so that it would be able to obtain a large share of the market for these types of drugs.

4. Defendant's representations that VIOXX® was safer than traditional NSAIDs was false, and despite its marketing and promotion as a safer alternative to traditional NSAIDs, VIOXX® also posed a risk of ulcers and gastrointestinal side effects. Moreover, VIOXX® produced a high rate of cardiovascular events, including heart attacks and strokes, and Defendant intentionally failed to disclose the level of risk of cardiovascular events caused by the drug.

5. Defendant was aware that by their false and misleading marketing and sales practices they would be able to prevent Mississippi agencies and instrumentalities and Mississippi physicians and its citizens from discovering, through reasonable diligence, the true risks associated with the ingestion of VIOXX®.

6. Fair and honest marketing of pharmaceuticals is a matter of great importance to the State of Mississippi and its citizens. Mississippi spends millions and millions of dollars each year on prescription drugs under its prescription drug programs. Expenditures by the State and its agencies and instrumentalities for prescription drug reimbursement have increased dramatically in the past several years as a result of Defendant's marketing schemes.

7. Plaintiff, the State of Mississippi (the "State"), by and through Mississippi Attorney General Jim Hood, brings this action:

(a) to recover amounts paid for the drug VIOXX® by the State, through its agencies and instrumentalities, as a result of the fraudulent conduct of Defendant;

(b) to recover the amounts the State has paid for its percentage share of VIOXX®, on behalf of the Mississippi citizens who are eligible for Medicaid;

(c) to recover the costs incurred by the State through its agencies and instrumentalities, relating to the medical treatment rendered to beneficiaries of State programs, and reimbursed by the State, as a result of the ingestion of VIOXX®; and

(d) to enjoin Defendant from continuing to perpetrate these marketing practices, to require Defendant to publicly disclose the true and actual risks of its drugs to potential users and purchasers, and to impose civil penalties against Defendant for its fraudulent practices.

PARTIES

8. Mississippi Attorney General Jim Hood is authorized to bring this action on behalf of the State under the Mississippi Constitution of 1890, pursuant to Mississippi statutes providing for certain of the causes of action herein, including, among others, § 7-5-1, Miss. Code Ann. (1972) and § 43-13-1 through § 43-1-145, Miss. Code Ann. (1972), as well as by common law.

9. Defendant, Merck & Co., Inc., "Merck" is a New Jersey corporation with its principal place of business in Whitehouse Station, New Jersey. Merck is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are reimbursed by State Medicaid agencies nationwide, including Mississippi's Division of Medicaid. Numerous pharmaceuticals are sold by Merck and reimbursed by the State under Mississippi's Medicaid program, and these drugs included VIOXX®. The State, through its agencies and instrumentalities has paid millions of dollars for reimbursement of such drugs manufactured by Merck.

JURISDICTION AND VENUE

10. Jurisdiction is proper as Plaintiff alleges only claims arising under the laws of the State of Mississippi. Venue is proper in the First Judicial District of Hinds County, Mississippi, pursuant to Mississippi statutory authority, including, § 43-13-223, § 43-13-301, § 75-24-9, Miss. Code Ann. (1972).

FACTUAL BACKGROUND

11. The State, through programs administered by its various agencies and instrumentalities pays for medical benefits, including prescription drugs, for qualifying Mississippians. These programs reimburse physicians and pharmacists for drugs prescribed for, and dispensed to, qualified recipients.

12. Reimbursement for prescription drugs under State programs are authorized by statute, for example, § 43-13-117 Miss. Code Ann. (1972). Pursuant to statute, the State agencies and instrumentalities have adopted a list of drugs which are covered without prior authorization. In determining which drugs will be included on the list, the administrators of the State's programs consider information provided by prescription drug manufacturers regarding the safety of the drug and the efficacy of the drug as compared to less expensive alternatives.

13. When a drug manufacturer reports false and misleading information concerning the safety of its product, and its effectiveness as compared with less expensive alternative drugs, and/or conceals this information from physicians and the State agencies and instrumentalities, the determination made by the agencies and instrumentalities with respect to the drug's inclusion on its preferred drug list or reimbursable formulary is flawed. These circumstances result in drug reimbursement payments to drug providers by the State of Mississippi for drugs which should not have been approved for prescription by medical providers. At all times relevant to this

action, Defendant was aware of the State agencies' drug utilization review, approval and reimbursement formulas.

14. Defendant provided to the State and its agencies and its instrumentalities, directly and/or through submission of reports to drug utilization review committees, what was purported to be accurate data for the Merck product, VIOXX®. In addition, Merck's intense marketing and sales efforts directed directly at the State of Mississippi, and to the general public, were carried out in such a manner as to create the false perception by the public, generally, and Mississippians, specifically, that its drug VIOXX® was safe, effective, and a better source of pain relief than other less expensive alternative medications.

15. Defendant has affirmatively endeavored to conceal the actual nature of the drug VIOXX®, its attendant risks, and its lack of reported efficacy. As a result of this concealment, Defendant prevented third parties, including the State of Mississippi and its agencies and instrumentalities, from determining the true nature of the drug VIOXX®, and at all times relevant to this action, Defendant knew that information accurately reflecting the dangers associated with VIOXX® and its lack of substantial effectiveness as compared to other drugs was not available to the State and its agencies and instrumentalities. Defendant was aware that at all relevant times, the State's agencies used, and relied on, the information regarding VIOXX® as provided by Defendant to the State and its agencies, directly and indirectly, to determine the amounts paid for reimbursement of prescription drugs.

16. Defendant intended that the drug information provided to the State and its agencies, both directly and indirectly, would be used by the State and its agencies to determine whether VIOXX® would be on the State's formulary, and in what amount the various State programs would reimburse pharmacy providers for VIOXX®.

17. At all relevant times, the State, its agencies and instrumentalities had no knowledge of, and had no means of learning, the actual nature and efficacy of VIOXX®. Rather, the State, its agencies and instrumentalities obtained this information from Defendant, directly and indirectly, and reasonably relied on this information in determining the State's pharmacy benefits relative to VIOXX®.

DEFENDANT'S FALSE AND MISLEADING STATEMENTS

A. 1999 False and Misleading Statements.

18. During the time period from May 21, 1999, when VIOXX® was first introduced on the market, through December 1999, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts concerning the safety and efficacy of VIOXX®, including the following:

1. Merck Announces FDA Approval of VIOXX®

19. On May 21, 1999, Merck issued a press release (the "May 21, 1999 Press Release") in which it announced that the FDA had approved VIOXX® for the relief of osteoarthritis, menstrual pain and other forms of acute pain. Merck stated that the most common side effects reported in clinical trials with VIOXX® were upper-respiratory infection, diarrhea and nausea. The press release stated that VIOXX® should be available in pharmacies by mid-June, 1999. The press release failed to disclose material adverse information known to Merck concerning the cardiovascular risks associated with VIOXX®. Defendant was aware of these risks from internal studies, including Study 090, the results of which Defendant failed to disclose to the FDA or to the public.

2. Merck Promotes VIOXX® while Purposely Failing to Disclose The Cardiovascular Risks of the Drug

20. On October 19, 1999, the Company issued a press release entitled "Publication shows new medicine VIOXX® relieved Menstrual Pain" (the "October 19, 1999 Press Release".) The October 19, 1999 Press Release stated in pertinent part "Since its approval by the FDA in May, more than 2.2 million prescriptions have been written for VIOXX® in the United States, making it one of the most successful product introductions in the pharmaceutical industry's history." The October 19, 1999 Press Release failed to disclose material adverse information known to Merck concerning the serious cardiovascular risks associated with VIOXX®.

21. On October 25, 1999, the Company issued a press release (the "October 25, 1999 Press Release") in which the Company stated that VIOXX® "produced fewer ulcers in osteoarthritis patients than patients taking ibuprofen." Merck announced the results of a new study showing that osteoarthritis patients taking VIOXX® developed fewer stomach ulcers than patients taking ibuprofen. The October 25, 1999 Press Release failed to disclose the material adverse information known to Merck concerning the cardiovascular risks associated with VIOXX® that threatened VIOXX®'s medical and commercial viability.

22. On November 23, 1999, the Company issued a press release (the "November 23, 1999 Press Release") entitled "In a Study Published in the Journal of the American Medical Association, VIOXX® Significantly Reduced Risk of Serious Gastrointestinal Side Effects Compared to Other NSAIDS." The November 23, 1999 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> VIOXX®, the new medicine for osteoarthritis from Merck & Co., Inc., significantly reduced the risk of gastrointestinal (GI) side effects such as symptomatic ulcers and bleeding compared to three

> commonly prescribed non-steroidal anti-inflammatory drugs (NSAIDs), according to a new study being published in tomorrow's issue of the Journal of the American Medical Association.
>
> ***
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> Common side effects reported in clinical trials with VIOXX® were upper-respiratory infection, diarrhea, nausea and high blood pressure. People who have had an allergic reaction to VIOXX®, aspirin or other NSAIDs should not take VIOXX®. Safety and effectiveness in children below the age of 18 has not been studied.

23. The November 23, 1999 Press Release failed to disclose material adverse information concerning cardiovascular risks associated with VIOXX®, including results of Study 090 which concluded that VIOXX® users were 6 times more likely than non-VIOXX® users to have severe cardiovascular events.

24. Each of the Defendant's statements made in 1999 concerning VIOXX® was materially false and misleading when issued, because each statement failed to disclose information known to the Defendant, that VIOXX® was associated with negative cardiovascular events. The true but concealed and/or misrepresented facts included, but were not limited to:

- Merck's unpublished Study 090 concluded that VIOXX® users were 6 times more likely to have severe cardiovascular events than users of other NSAIDS;
- Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved VIOXX® for prescription use, Merck knew of the VIOXX®-related medical risks;
- Substantial data existed in 1999 that VIOXX® was associated with a higher risk of cardiovascular events than other NSAIDs;
- On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendant for misleading the public by using deceptive promotional materials that suggested VIOXX® had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence; and
- The Company could not maintain the positive VIOXX® sales results that it was experiencing because of the known risks to VIOXX®'s medical and commercial viability.

B. 2000 Events and False and Misleading Statements

25. In 2000, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts concerning the safety and efficacy of VIOXX®, including the following:

1. Merck Announces Results of VIGOR Study, But Conceals Findings of Cardiovascular Risks Associated with VIOXX®

26. On March 27, 2000 Merck issued a press release (the "March 27, 2000 Press Release") entitled "Merck Informs Investigators of Preliminary Results of Gastrointestinal Outcomes Study With VIOXX®." The March 27, 2000 Press Release commented upon the results of the VIGOR study previously discussed in this Complaint. In the March 27, 2000 Press Release, Merck stated that according to the VIGOR study results, "[a]mong patients treated with VIOXX®, there was a significantly reduced incidence of serious gastrointestinal events compared to patients treated with Naproxen." The March 27, 2000 Press Release also made the following materially false and misleading statements and/or omissions of material facts:

> In addition, significantly fewer thromboembolic events were observed in patients taking Naproxen in this GI outcomes study, which is consistent with Naproxen's ability to block platelet aggregation. This effect on these events had not been observed previously in any clinical studies for Naproxen. **VIOXX®, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects.** As a result, Merck is notifying investigators, who are conducting other Merck studies with VIOXX® or another investigational medicine in the same class, of protocol amendments to allow the addition of low-dose aspiring where appropriate.
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> An extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with VIOXX®, **showed no indication of a difference in the incidence of thromboembolic events between VIOXX®, placebo and comparator NSAIDs** (emphasis added).

27. The March 27, 2000 Press Release failed to disclose known material negative information concerning the cardiovascular risks associated with VIOXX® that threatened VIOXX®'s medical and commercial viability. Moreover, the March 27, 2000 Press Release misleadingly and falsely attributed the higher incidence of cardiac events observed in the VIGOR study to the putative cardio protective characteristics of Naproxen.

3. Merck Falsely Touts VIOXX®'s Safety Profile as "Excellent"

28. On September 8, 2000, Merck issued a Press Release (the "September 8, 2000 Press Release") entitled "Merck Confirms Excellent Safety Profile of VIOXX®." In the September 8, 2000 Press Release, Defendant made the following materially false and misleading statements and/or omissions of material fact:

> Merck & Co., Inc. confirmed today that a routine report issued by the U.K. regulatory authority demonstrates the excellent safety profile of VIOXX® (rofecoxib), Merck's medicine for osteoarthritis. The report was issued by the U.K. Medicines Control Agency (MCA) because VIOXX® has now been available in the U.K. for one year. During that time, more than 550,000 prescriptions for VIOXX® were written for patients in the U.K. The events listed were reported by physicians as events that occurred while patients were taking VIOXX®, and were not specifically attributed to VIOXX®.
>
> **Merck considers patients safety to be of the utmost importance, and we routinely monitor all of our medicines. What was reported by the MCA confirms what we've seen in the thousands of patients in our controlled clinical trials and in clinical practice: VIOXX® has an excellent safety profile,** says Eve Slater, M.D. senior vice president, Clinical and Regulatory Development, Merck Research Laboratories. (emphasis added)

29. The September 8, 2000 Press Release failed to disclose material adverse information known to Merck regarding the cardiovascular risks associated with VIOXX®, including the results of Study 090 and VIGOR which showed that VIOXX® presented a high risk of negative cardiovascular events.

30. On November 3, 2000, Defendant issued a press release (the "November 3, 2000 Press Release") entitled "VIOXX® Significantly Reduced Pain After Dental Surgery to a Greater Degree Compared to Codeine with Acetaminophen in New Study." In the November 3, 2000 Press Release, Defendant announced the results of a study which showed that "VIOXX® 50mg significantly reduced moderate to severe acute pain after dental surgery to a greater degree compared to codeine 60 mg combined with acetaminophen 600 mg." The November 3, 2000 Press Release stated in pertinent part:

> "Overall, VIOXX® was well tolerated in this study, and overall rate of side effects on VIOXX® was generally similar to placebo. Significantly fewer patients taking VIOXX® experienced side effects than patients taking codeine with acetaminophen."

31. The November 3, 2000 Press Release failed to disclose material adverse information known to Merck concerning the cardiovascular risks associated with VIOXX®.

32. Each of the Defendant's statements made from January 1, 2000 through December 31, 2000 concerning VIOXX® was materially false and misleading when made, because each statement failed to disclose material and statistically significant information known to the Company that VIOXX® was associated with cardiovascular events. In this regard, the Merck Defendant failed to disclose:

- Merck's unpublished Study 090 concluded that VIOXX® users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

- Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved VIOXX® for prescription use, Merck knew of the VIOXX®-related medical risks;

- Substantial data existed in 1999 that VIOXX® was associated with a higher risk of cardiovascular events than other NSAIDs; and

- On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendant for misleading the public by using deceptive promotional

materials that suggested VIOXX® had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

• The Merck Defendant knew that the negative cardiovascular events were not due to the cardioprotective properties of Naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendant observed in Study 090 and VIGOR; and

• VIOXX®'s safety profile was not "excellent" as the Merck Defendant claimed, but was instead marked by an unacceptably high risk of negative cardiovascular events.

C. 2001 Events and False and Misleading Statements

33. In 2001, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts concerning the safety and efficacy of VIOXX®, including the following:

1. Merck Announces the FDA Advisory Committee Meeting To Modify VIOXX® Label

34. On February 8, 2001, Merck issued a press release (the "February 8, 2001 Press Release") entitled "FDA Arthritis Advisory Committee Reviews Merck's Application for Revised Labeling for VIOXX® Based on VIOXX® Gastrointestinal Outcomes Study." In the February 8, 2001 Press Release, Merck announced that the FDA Advisory Committee had agreed that results from the VIGOR study -- that VIOXX® significantly reduced serious GI side effects by half compared to a commonly used dose of Naproxen in rheumatoid arthritis patients -- be included in the labeling for VIOXX®. The February 8, 2001 Press Release made the following materially false and misleading statements:

> Merck is confident that the data presented today support the excellent safety profile of VIOXX®, and we look forward to further discussions with the FDA to complete the review of our application to modify the labeling for VIOXX®, said Eve Slater, M.D., senior vice president, Clinical and Regulatory Development, Merck Research Laboratories.

35. The February 8, 2001 Press Release failed to disclose known information concerning significantly increased risks of cardiovascular problems associated with VIOXX®, and failed to disclose that VIOXX® had, at best, a questionable safety profile.

2. Merck Touts FDA Approval of Revised Label for VIOXX®

36. On April 10, 2001, Merck issued a press release (the "April 10, 2001 Press Release") entitled "Merck Receives 'Approvable' Letter for VIOXX® from FDA on Application for Revised Labeling Based on VIOXX® Gastrointestinal Outcomes Study." The April 10, 2001 Press Release contained the following materially false and misleading statements and omissions of material fact:

> Merck & Co., Inc. today confirmed that it has received an approvable letter from the U.S. Food and Drug Administration for the Company's application for changes to the prescribing information for its osteoarthritis and acute pain medicine VIOXX® (rofecoxib).
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> ***
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> The Company submitted a supplemental new drug application on June 29, 2000, seeking changes to reflect results from the VIOXX® Gastrointestinal Outcomes Research (VIGOR) study. The Company is confident in the comprehensive data that support the excellent gastrointestinal and overall safety profile of VIOXX®.

37. This press release failed to disclose what the Merck Defendant knew at the time to be a significant risk of serious cardiovascular events.

38. On May 1, 2001, *Med Ad News* published an article entitled "Determined to overtake rival Celebrex, Merck has made VIOXX® the fastest-growing brand," in which a senior Vice President of marketing at Merck, was quoted as stating:

> VIOXX® has broken the traditional new nonsteroidal anti-inflammatory drug shape of the curve because the product has continued to grow way beyond the normal six-month time frame when the older new nonsteroidal anti-inflammatory drugs and even Celebrex tended to flatten off. VIOXX® has continued to grow and that is a result of the good product that we have, the satisfaction that it is providing to patients and physicians, and the strong marketing and marketing messages that we have put into the marketplace.

39. The foregoing statement by the Defendant failed to disclose material adverse information known to it concerning the cardiovascular risks associated with VIOXX®. The statements by the Defendant were directly contradicted by its internal e-mails and documents and by Merck-sponsored studies described elsewhere herein.

40. On May 11, 2001, Merck issued a press release (the "May 11, 2001 Press Release") entitled "Merck Confirms Renal Safety Of VIOXX®." The May 11, 2001 Press Release stated that in comparative studies between VIOXX®, celecoxib and acetaminophen, there were no significant differences in the incidents of renal effects, such as hypertension and edema, and that "in these studies, the incidences of increased blood pressure and lower extremity edema among patients taking VIOXX® were similar to those of the comparator NSAIDs; there were no significant differences between the active treatment groups." The May 11, 2001 Press Release failed to disclose material adverse information known to the Defendant concerning the cardiovascular risks associated with VIOXX®, including those specifically revealed by this Merck sponsored study.

41. On May 22, 2001, Merck issued a press release (the "May 22, 2001 Press Release") entitled "Merck Confirms Favorable Cardiovascular Safety Profile of VIOXX®." In the May 22, 2001 Press Release, the Company made the following materially false and misleading statements:

> In response to news and analyst reports of data the Company first released a year ago, Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of VIOXX® (rofecoxib), its medicine that selectively inhibits COX-2.

42. The May 22, 2001 Press Release failed to disclose material adverse information known to the Defendant concerning the cardiovascular risks associated with VIOXX®. Among other things, the Defendant failed to disclose the contents of Merck internal e-mails and

documents, Study 090, the VIGOR study, the results of Merck-sponsored research and studies, and the conclusions that Merck aggressively sought to sponsor.

3. Merck Promotes False Cardiovascular Safety Profile of VIOXX®

43. On June 13, 2001, Merck issued a press release (the "June 13, 2001 Press Release") entitled "In New 28,000-Patient Meta-Analysis of Cardiovascular Events: Event Rates With VIOXX® were Similar to Placebo, Similar to Widely Prescribed NSAIDs Ibuprofen, Diclofenac and Nabumetone; Event Rate was Reduced with Naproxen." The June 13, 2001 Press Release made, among others, the following materially false and misleading statements and/or omissions of material fact:

> The rates of cardiovascular events seen in patients taking VIOXX® were similar to those seen with both placebo and with the widely prescribed NSAIDs diclofenac, ibuprofen and nabumetone, while the event rate was lower for Naproxen compared to VIOXX®, said Alise Reicin, M.D., Senior Director, Merck Research Laboratories. The meta-analysis was strengthened by the fact that the majority of the data included in it was from studies six months or longer in duration.
>
> Aspirin blocks platelet aggregation by more than 90 percent by binding irreversibly to platelets. ***This property is believed to be responsible for its cardioprotective effect. It is reported in the scientific literature that Naproxen blocks platelet aggregation by about 90 percent if given every 12 hours at its recommended dose –as provided for in the studies with VIOXX®.*** This anti-platelet effect of Naproxen has not been observed among the other comparator NSAIDs; it has been reported that they do not block platelet aggregation in a sustained manner. (emphasis added)

44. The June 13, 2001 Press Release failed to disclose material adverse information known to the Defendant concerning the risk of cardiovascular events associated with VIOXX®. Among other things, the statements directly contradicted Defendant's e-mails and the results of internal studies like Study 090.

4. Merck Misrepresents Results of *Journal of American Medical Association* Study

45. On August 21, 2001, *Dow Jones Business News* published an article entitled "*JAMA* Article Suggests VIOXX® and Celebrex Raise Cardiovascular Risks" (the "First August 21, 2001 Article"). The First August 21, 2001 Article, which appears to have been based upon Dow Jones' receipt of an early copy of the article to be published in *JAMA*, discussed the Cleveland Clinic study and stated in pertinent part:

> An analysis of clinical trials suggests a potential increase in the rate of heart attack, stroke and other cardiovascular events among patients treated with VIOXX® from Merck & Co. Inc. (MRK) and Celebrex from Pharmacia Corp. (PHA) and Pfizer Inc. (PFE), according to an article in *The Journal of the American Medical Association*. Merck said in a prepared statement it stands behind the overall and cardiovascular safety profile and the favorable gastrointestinal profile of VIOXX®. The Company further contended, "***Extensive cardiovascular data already exist on VIOXX® and that these data, which weren't incorporated into the authors' analysis, suggest that there is no increase in the risk of cardiovascular events as a result of treatment with VIOXX®.***" (emphasis added)

46. The foregoing statement, failed to disclose material facts concerning the cardiovascular risks that VIOXX® presented and symbolized Defendant' efforts to suppress and distort the truth that VIOXX® was affirmatively dangerous.

47. Also on August 21, 2001, *Dow Jones Newswires* published an article entitled "VIOXX®, Celebrex Use Raises Cardiovascular Concerns-Study" (the "Second August 21, 2001 Article"). The Second August 21, 2001 Article further addressed the drug makers' responses to the findings of the Cleveland Clinic: "First, these drug makers do not believe their respective COX-2 inhibitors increases [sic] the risk of heart attack, stroke, unstable angina, and other cardiovascular events. The drug makers separately insist that their drugs are effective and safe, overall and with respect to the heart and cardiovascular system." The Second August 21, 2001

Article described the comments of the senior director of cardiovascular clinical research at Merck:

> "We can't explain what is behind that observation and the authors point out the lower rate of cardiovascular events in those receiving Naproxen may be the result of the beneficial effects of Naproxen, which has aspirin-like profile in preventing platelet aggregation."
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> Understanding the relationship warrants further studies with placebo, said Demopoulos. ***But Merck has created an extensive body of cardiovascular data on VIOXX®, which was excluded from the author and analysis, which suggests VIOXX® doesn't increase the risk of cardiovascular events, she added.***

48. The Second August 21, 2001 Article failed to disclose material adverse information known to Merck concerning the cardiovascular risks associated with VIOXX®. Instead, the Defendant's statement affirmatively misrepresented VIOXX®'s safety profile in a very direct contradiction of Defendant's internal e-mails and prior studies by Merck and others.

49. On August 23, 2001, the Company issued a press release (the "August 23, 2001 Press Release") entitled "Merck Stands Behind the Cardiovascular Safety Profile of VIOXX®," which stated in relevant part:

> Merck & Co., Inc. today, said the Company stands behind the overall and cardiovascular safety profile and the favorable gastrointestinal (GI) profile of VIOXX®. Merck believes VIOXX® is an appropriate and efficacious therapy for the relief of the signs and symptoms of osteoarthritis and the management of acute pain in adults.
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> The authors [of the *JAMA* article] say that more data are needed on the cardiovascular profile of COX-2 inhibitors. However, Merck believes that extensive cardiovascular data already exist on VIOXX® and that these data -- which were not incorporated into the author's analysis -- suggest that there is no increase in the risk of cardiovascular events as a result of treatment with VIOXX®.

50. The August 23, 2001 Press Release failed to disclose material adverse information known to the Defendant concerning the cardiovascular risks associated with VIOXX®, and misrepresented VIOXX®'s safety profile. The August 23, 2001 Press Release -- apparently

designed to falsely reassure both patients and prescribers that VIOXX® was safe -- directly contradicted Defendant's internal documents and other materials that demonstrated conclusively the statistically significant risks known to the Defendant even before VIOXX® was introduced.

5. Merck Refutes Statements in September 17, 2001 FDA Letter

51. On September 17, 2001, as described above, the FDA sent the Company a letter (the "September 17, 2001 FDA Letter") stating: "As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed your promotional activities and materials and has concluded that they are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations."

52. The September 17, 2001 FDA Letter went on to state:

> You have engaged in a promotional campaign for VIOXX® that minimizes the potentially serious cardiovascular findings that were observed in the VIOXX® Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for VIOXX®. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on VIOXX® were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (Naproxen).

53. The September 17, 2001 FDA Letter ordered the Defendant to stop using certain promotional materials and to send a letter to healthcare providers to correct any false impressions that came from Merck's marketing of VIOXX®.

54. The September 17, 2001 FDA Letter referenced the December 19, 1999 FDA Letter, adding that Merck's "misrepresentation of the safety profile for VIOXX® is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for VIOXX® that also misrepresented VIOXX®'s safety profile."

55. On September 24, 2001, Reuters published an article entitled "Merck VIOXX® Promotions Said Misleading on Safety," in which it described the September 17, 2004 FDA Letter. The September 24, 2001 article quoted a Merck spokeswoman, who stated that the Company was developing a response to the FDA that it planned to submit by October 1, 2001:

> **"We continue to stand behind the overall safety and cardiovascular safety of VIOXX®."**

56. Defendant's statements in this regard were false and misleading when made and contradicted Merck's internal documents and the results funded of Merck-funded studies like Study 090.

57. Each of the statements made from January 2001 through December 2001 concerning VIOXX® was materially false and misleading when made, because each statement failed to disclose material facts needed to make the statements made not misleading in light of the circumstances under which they were made. In fact, Defendant knew that VIOXX® was associated with a significant risk of cardiac events. The true but concealed and/or misrepresented facts included, but were not limited to:

- Merck's press releases "reconfirming the favorable cardiovascular safety profile of VIOXX®" during 2001 were unfounded, because the Defendant knew that VIOXX® was associated with high cardiovascular risks;

- Merck's announcements refuting the Cleveland Clinic study results in *JAMA* and stating that the Company stood behind the safety profile of VIOXX® were unfounded, as the Defendant was aware that VIOXX® in fact caused an increase in adverse cardiovascular events;

- The Revised label for VIOXX® that Merck announced in April 2001 failed to disclose the severe cardiovascular risks that the Defendant had already observed in, among other things, Study 090 and VIGOR;

- The VIOXX® promotional activities that the FDA condemned in the September 17, 2001 FDA Letter stemmed from Defendant's deliberate efforts to conceal VIOXX®'s known risks;

• Merck's unpublished Study 090 concluded that VIOXX® users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

• Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved VIOXX® for prescription use, the Defendant knew of the VIOXX®-related medical risks;

• Substantial data existed in 1999 that VIOXX® was associated with a higher risk of cardiovascular events than other NSAIDs; and • On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendant for misleading the public by using deceptive promotional materials that suggested VIOXX® had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

• The Merck Defendant knew that the negative cardiovascular events were not due to the cardioprotective properties of Naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendant observed in Study 090; and

• VIOXX®'s safety profile was not "excellent" as the Merck Defendant claimed, but was instead marked by an unacceptably high risk of negative cardiovascular events.

D. 2002 Events and False and Misleading Statements

58. In 2002, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts concerning the safety and efficacy of VIOXX®, including the following:

1. Merck Promotes New Changes to VIOXX®'s Label While Affirmatively Concealing the Significant Medical and Commercial Risks Associated with VIOXX®

59. On April 11, 2002, the Company issued a press release (the "April 11, 2002 Press Release") entitled "Merck Re-Issues New Release for VIOXX® -rofecoxib-With Prescribing Information Attached." The April 11, 2002 Press Release described a conference call held that day by Merck for pharmaceutical industry analysts, during which Merck re-released the announcement of FDA-approved changes to the label for VIOXX®. The April 11, 2002 Press Release stated in pertinent part:

VIOXX® is now the first and only medicine that selectively inhibits the COX-2 enzyme that is proven to reduce the risk of developing clinically important

> gastrointestinal (GI) side effects in patients with or without risk factors for such GI side effects compared to the non-steroidal anti-inflammatory drug (NSAID) Naproxen. In VIGOR, VIOXX® 50 mg -- a dose two-times the highest recommended chronic dose -- significantly reduced serious GI side effects, including perforations, obstructions, ulcers and bleeds, by 54 percent compared to a commonly used dose of Naproxen (1,000 mg) in rheumatoid arthritis patients. The GI safety benefit compared to Naproxen, as shown in VIGOR, now appears as a modification to the GI Warning section of the prescribing information, a section included in the prescribing information for all NSAIDs, including those that selectively inhibit Cox-2.
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> "Merck is confident in the efficacy and safety profile of VIOXX®. VIGOR was a rigorous test of the GI safety of VIOXX® versus Naproxen and based on that study, the FDA has approved a modification to the standard GI warning section. Our label now reads: 'Although the risk of GI toxicity is not completely eliminated with VIOXX®, the results of the VIGOR study demonstrate that in patients treated with VIOXX®, the risk of GI toxicity with VIOXX® 50 mg once daily is significantly less than with Naproxen 500 mg twice daily,'" said Edward M. Scolnick, M.D., executive vice president, science and technology, and president, Merck Research Laboratories, Merck & Co., Inc.

60. The April 11, 2002 Press Release failed to disclose information known to the Defendant indicating that VIOXX® presented cardiovascular risks. The statements in the April 11, 2002 Press Release were precisely the type of statements condemned as false and misleading by the FDA in the letters it sent to Merck in December 1999 and September 2001.

61. On April 18, 2002, the *Associated Press Online* published an article (the "April 18, 2002 *AP Online* Article") entitled "Risks of Arthritis Drugs Studied," which stated in pertinent part:

> "There's growing suspicion that switching from aspirin to a more stomach-friendly arthritis drug could increase some people's risk of heart attacks -- and a study suggests the reason: a drug caused chemical imbalance that spurs blood clots. . . . VIOXX® maker Merck & Co. dismisses the study as irrelevant, because it is in mice and presumes an effect in the human body far larger than the drug actually causes." The April 18, 2002 *AP Online* Article further stated: "But the study looked at mice that had completely inhibited prostacyclin, while cox-2 drugs inhibit the chemical only half as much, said Merck scientist Dr. Alise Reicin. She said the study contributed no new information to the debate, but Merck plans further safety studies to deal with the issue, although she would not provide details."

• Substantial data existed in 1999 that VIOXX® was associated with a higher risk of cardiovascular events than other NSAIDs; and

• On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendant for misleading the public by using deceptive promotional materials that suggested VIOXX® had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

• Merck knew that the negative cardiovascular events were not due to the cardioprotective properties of Naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendant observed in Study 090; and

• VIOXX®'s safety profile was not "excellent" as the Merck Defendant claimed, but was instead marked by an unacceptably high risk of negative cardiovascular events.

E. 2003 Events and False and Misleading Statements

64. In 2003, the Defendant made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts concerning the safety and efficacy of VIOXX®, including the following:

1. Merck Continues to Tout Vioxx as Safe, Refuting the Results of a Study Linking Vioxx® to Cardiac Events

65. On October 30, 2003, *The Wall Street Journal* published an article (the "October 30, 2003 Article") entitled "Vioxx Study Sees Heart-Attack Risk--Merck Funded Research After Concerns Were Raised About Its Painkilling Drug." The article discussed a study conducted at Harvard University-affiliated Brigham & Women's Hospital in Boston, which found "an increased risk of heart attack, or acute myocardial infarction, compared with patients taking a competing painkiller, Celebrex, from Pfizer Inc. The researchers also found that VIOXX®, which has annual sales of $2.5 billion a year, was linked to an increased heart-attack risk compared with patients not taking any painkillers." The October 30, 2003 Article continued:

> The new study, Dr. Topol said, "greatly substantiates our concern about the cardiac side effects." He observed that the possible cardiac effects of Vioxx appear "worse with the higher doses." Merck discounted the